

MPATHY MEDICAL DEVICES, LTD.  
OMNISURE URETHRAL SLING  
SPECIAL 510(k) NOTIFICATION

15. 510(k) SUMMARY OF SAFETY & EFFECTIVENESS

AUG 12 2009

<b>SUBMITTER</b>	Ms Melissa Peloquin Director of Office Administration Mpathy Medical Devices Inc. 175 Paramount Drive Raynham, MA 02767
<b>CONTACT PERSON</b>	Dr Caroline Stretton Quality & Regulatory Affairs Director Mpathy Medical Devices, Ltd. 208 Wright Business Centre Lonmay Road Glasgow G33 4EL (United Kingdom)
<b>DATE PREPARED</b>	22 July 2009
<b>CLASSIFICATION</b>	Surgical Mesh (Product Code FTL) is a Class II device per 21 CFR 878.3300
<b>COMMON NAME</b>	Surgical Mesh
<b>PROPRIETARY NAME</b>	Omnisure™ Urethral Sling
<b>PREDICATE DEVICE</b>	K073647 – Minitape® Extra Urethral Sling (Mpathy Medical Devices) K011251, K013355, K021263 & K020663 - SPARC Sling System (American Medical Systems) K974098 - TVT (Ethicon) K091180 - Minitape® O Urethral Sling (Mpathy Medical Devices)
<b>DEVICE DESCRIPTION</b>	Omnisure™ Urethral Sling is a surgical mesh intended to be used as a pubourethral sling for the treatment of female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The proprietary mesh is supplied along with ancillary tools for placement of the device.
<b>INDICATIONS</b>	The device is supplied sterile. Omnisure™ Urethral Sling is indicated for the surgical treatment of urodynamically proven female urinary stress incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

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**TECHNOLOGICAL CHARACTERISTICS**    Omnisure™ Urethral Sling has the same intended use, general design, material and fundamental scientific technology as the predicate Minitape Extra Urethral Sling (K073647).

**TESTING**    The components of the Omnisure™ device are substantially equivalent to the predicate Minitape® Extra device (K073647), which has been subjected to biocompatibility and mechanical testing.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center - WO66-G609  
Silver Spring, MD 20993-0002

Mpathy Medical Devices, Ltd.  
% Mpathy Medical Devices, Inc.  
Ms. Melissa Peloquin  
Director of Office Administration  
175 Paramount Drive  
Raynham, Massachusetts 02767

AUG 12 2009

Re: K092203  
Trade/Device Name: Omnisure™ Urethral Sling  
Regulation Number: 21 CFR 878.3300  
Regulation Name: Surgical mesh  
Regulatory Class: Class II  
Product Code: FTL  
Dated: July 22, 2009  
Received: July 22, 2009

Dear Ms. Peloquin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

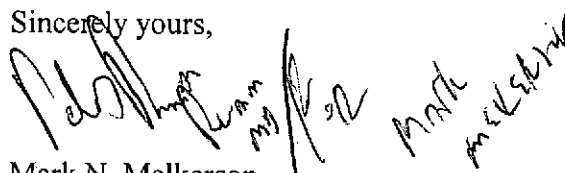
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', is written over the typed name and title.

Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K092203  
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MPATHY MEDICAL DEVICES, LTD.  
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**14. STATEMENT FOR INDICATIONS FOR USE**

**510(k) Number:** \_\_\_\_\_

**Device Name:** Omnisure™ Urethral Sling

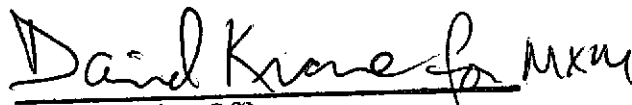
**Indications for Use:** Omnisure™ Urethral Sling is indicated for the surgical treatment of urodynamically proven female urinary stress incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

**Prescription Use:** Yes

DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

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Concurrence of CDRH, Office of Device Evaluation

  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K092203